IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ENDO PHARMACEUTICALS INC., Plaintiffs, v. ROXANE LABORATORIES, INC. Defendants.	C.A. No. 13-cv-3288-TPG
ENDO PHARMACEUTICALS INC., and GRÜNETHAL GMBH Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC Defendants.	C.A. No. 13-cv-8115-TPG
ENDO PHARMACEUTICALS INC., Plaintiffs, v. RANBAXY LABORATORIES LTD., RANBAXY INC. and RANBAXY PHARMACEUTICALS INC., Defendants.	C.A. No. 13-cv-8597-TPG

ENDO PHARMACEUTICALS INC., Plaintiffs, v. RANBAXY LABORATORIES LTD., RANBAXY INC. and RANBAXY PHARMACEUTICALS INC., Defendants.	C.A. No. 13-cv-4343-TPG

ENDO PHARMACEUTICALS INC.'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION FOR REDUCTION IN THE NUMBER OF ASSERTED CLAIMS

Defendants' motion for reducing the number of claims Endo is asserting is unnecessary and premature. In fact, Endo has already substantially narrowed its asserted claims, dropping two thirds of the claims that it originally asserted against the moving Defendants. While the Defendants seek an immediate additional reduction of the claims Endo asserts, further reduction at this time would prejudice Endo. Endo believes that fairness and judicial economy would both be served if Endo is allowed to identify a reasonable number of claims for trial once it has had the opportunity to evaluate the invalidity, non-infringement, and claim construction positions that Defendants are expected to present in detail for the first time in their expert reports.

BACKGROUND

Twelve related actions are currently pending before this Court concerning the various Defendants' attempts to market generic versions of Plaintiff Endo Pharmaceuticals Inc.'s ("Endo") Opana® ER tablets, in both the current crush resistant formulation and the discontinued original formulation. In these twelve related actions, plaintiffs Endo and Grünenthal GmbH (collectively "Plaintiffs") have asserted claims for infringement of six different patents. Only the three of these six patents that are owned by Endo are asserted against the moving Defendants Roxane Laboratories, Inc. ("Roxane"), Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC ("Amneal"), and Ranbaxy Laboratories Ltd., Ranbaxy Inc., and Ranbaxy Pharmaceuticals Inc. ("Ranbaxy") (collectively the "Moving Defendants"). Those three patents are U.S. Patent No. 8,309,122 (the "'122 Patent"), U.S. Patent No. 8,329,216 (the "'216 Patent"), and U.S. Patent No. 7,851,482 (the "'482 Patent").

Broadly speaking, the '122 and '216 patents relate to the dissolution profiles and biological properties of a twice-a-day extended release oxymorphone product, such as Endo's Opana® ER, while the '482 patent is directed to a specific purified form of oxymorphone hydrochloride that has a reduced amount of impurities. The remaining three patents, owned by

Grünenthal and directed to crush resistant formulations, are not asserted against the Moving Defendants.[1]

Endo initially alleged that each Moving Defendant infringed a total of 76 claims from the '122, '216, and '482 Patents (and that collectively, the Defendants in the twelve suits infringed a total of 130 claims from the six patents-in-suit).[2] As set forth in the proposed Case Management Order that Plaintiffs submitted to the Court on August 14, 2014 (C.A. No. 13-cv-3288-TPG, D.I. 77 Ex. A), in order to streamline the issues for trial, Plaintiffs proposed a staged process for narrowing the number of patent claims to be presented at trial—with a first reduction at the conclusion of fact discovery, and then a further reduction in the number of asserted claims after expert discovery is completed. Plaintiffs notified Defendants that they were about to provide a narrowed set of claims weeks before the Moving Defendants filed this motion.

Consistent with its proposed Case Management Order, Endo voluntarily and unilaterally served its narrowed list of claims on September 3, 2014, before the end of fact discovery. Endo reduced the number of claims asserted against each Moving Defendant to just 26 claims—that is, to roughly one-third the number of claims initially asserted.

Claim selection in these litigations is complex because the twelve different cases involve twelve different generic products, each with different formulations ("recipes," if you will). Accordingly, Endo has tailored its selection of asserted claims to the specific generic product at issue in each case. While Endo asserts the same 26 claims against each of the Moving Defendants, Endo is not asserting the same claims across all twelve related litigations. In fact, across the twelve related litigations, Plaintiffs initially asserted a total of 130 unique claims.

[1] Grünenthal is no longer a party to the Amneal action. Accordingly, there is no motion pending to reduce the number of the Grünenthal patent claims asserted.

[2] Declaration of Carl Gismervig ("Gismervig Decl.") (filed herewith) ¶3.

Plaintiffs have now voluntarily reduced the total set of asserted claims across all six patents-in-suit to 46 unique claims, with 26 to 44 claims asserted against each individual defendant.

ARGUMENT

1. Endo's Proposal for Limiting Claims is Reasonable

Plaintiffs have already begun to implement a reasonable process for identifying a limited set of claims for trial. As fact discovery is about to conclude, Plaintiffs recently reduced the number of asserted claims, and plan to make further reductions after the close of expert discovery in order to appropriately limit the number of claims to be presented at trial. Specifically, Plaintiffs have proposed to further narrow the number of claims asserted at trial to a total of 30 patent claims across the six patents-in-suit.

Defendants, however, insist that Endo should be further compelled to restrict itself immediately to no more than 5 patent claims from any one of the patents-in-suit. That proposal would allow Endo to assert up to 30 patent claims at trial—the same total number of claims that Endo proposes as an absolute cap on the number of claims for trial. While Defendants' proposal would allow the same number of claims, it would unreasonably restrict Endo's discretion in choosing which claims across which patents to assert. But Endo's proposal of an average number of five claims across the six patents-in-suit, rather than a strict limitation of five patent claims from any one patent, is consistent with cases that Moving Defendants themselves cite—*see, e.g.*, *High Point SARL v. Sprint Nextel Corp.*, 2010 WL 9497168, at *5 (D. Kan. Aug. 18, 2010) (allowing 20 claims across 4 patents); *Adobe Sys. Inc. v. Wowza Media Sys. LLC,* 2013 WL 9541126 (N.D. Cal. 2013) (allowing 20 claims across the asserted patents); *Masimo Corp. v. Philips Electronics North America Corp*, 918 F.Supp.2d 277, 286 (allowing 30 claims across the 7 asserted patents).

This flexibility in claim selection is especially important for the ’216 Patent, as not all claims that are asserted are asserted against the same Defendants. A strict limitation on the number of claims from the ’216 patent would severely impede Endo’s ability to individually select the proper claims to assert against each individual generic product.

2. **Endo Has Already Limited its Claims to Eliminate Redundancies**

Endo has already limited its claims to eliminate the redundancies that Moving Defendants identify in their motion. For example, Moving Defendants identify redundancies in the ’216 patent by comparing claim 13 to claim 21, claim 23 to claims 24-30, claim 36 to claim 41, and claim 49 to claim 66 (Brief in Support of Defendants’ Motion for Reduction in the Number of Asserted Claims, C.A. No. 13-cv-3288-TPG, D.I. 85 at 9-13) but ***Endo is not currently asserting any of the allegedly redundant claims***. For the remaining pairs of claims from the ’216 Patent that Moving Defendants identified as redundant in their motion, Endo has eliminated redundancies by electing to proceed on only one claim from each set of claims: for example, Endo is asserting claims 38, 40, and 42, but will not proceed with the claims 31, 35, and 37.

Notably, Plaintiffs offered to provide a narrowed set of claims before Moving Defendants filed their motion, but surprisingly the Moving Defendants chose to file their motion before the date that Plaintiffs proposed for serving the narrowed lists. Had the Moving Defendants waited until Plaintiffs served the shortened list of claims, they would have realized that many of their concerns were already resolved.

While the Moving Defendants also argue that the originally asserted claims are redundant because certain limitations appear in multiple claims, this argument does not support further reduction. For example, while the Moving Defendants stress that the first limitation of claim 1 of the ’216 Patent appears in 40 other claims, this repetition is both necessary and unsurprising.

The first limitation of claim 1 requires the use of oxymorphone—the active ingredient in Endo's Opana® ER tablets as well as all 12 of the generic products Endo accuses of infringement.

Next, the Moving Defendants argue that certain limitations are redundant because while similar, they use different language. To the extent the language is different, Plaintiffs will not know whether Defendants interpret any of these differences as significant to validity and infringement until Defendants provide their expert reports. Once Defendants have served expert reports, Plaintiffs will be able to choose the claims for trial which are most appropriate to assert in light of Defendants' arguments.

Moving Defendants' final argument—*i.e.*, that based on the number of claims previously asserted, Defendants will face the burdensome task of drafting repetitive expert reports, separately addressing each limitation of each claim—is similarly without merit. Even if Endo had not already limited its claims, this argument is simply incorrect. The decision cited by Moving Defendants, *In re Brimonidine*, does not require that parties serve repetitive expert reports, walking through each claim on a claim-by-claim basis. Instead the Federal Circuit noted that, as the parties had not presented validity arguments on a claim by claim basis ***at trial***, the court would look at the narrowest of the asserted claims to determine whether the defendants had established that each limitation was present in the prior art. 643 F.3d 1366, 1372 (Fed. Cir. 2011). While Defendants must show that their prior art references show all limitations of the asserted claims, they are not required to do so in an inefficient, needlessly repetitive claim-by-claim fashion.

In truth, the potential volume of Defendants' expert reports is largely self-inflicted. While Defendants had previously represented to this Court that they would address a limited set of issues relating to invalidity, Defendants now propose coming to trial with 60 unique prior art

references in unlimited combinations, as well as a variety of non-prior art attacks. The Moving Defendants' disclosures to date are insufficient to understand the combinations of references that Defendants actually plan to assert and the specifics of each of their possible attacks. Without knowing which of this multitude of arguments Defendants are going to actually present to the Court, Endo would be prejudiced by having to further reduce claims now. Endo simply cannot know which of its claims are most appropriate to assert in view of the defenses Defendants will actually raise.[3]

3. **This is Not the Proper Time for Additional Reductions to the Number of Asserted Claims**

Plaintiffs just recently reduced the number of asserted claims. Any further reduction should follow the close of expert discovery. Defendants move this Court to force Plaintiffs to prematurely reduce the number of asserted patent claims, before Plaintiffs have even seen the expert reports that detail the basis for and evidence in support of Defendants' non-infringement and invalidity defenses. That is unreasonable.

Plaintiffs' staged approach to reducing the number of asserted claims for trial is well supported by the case law, and is eminently sensible. For example, case law supports waiting until after claim construction to select a final narrowed set of claims, as those claim constructions will help Plaintiffs understand which claims are most appropriate to pursue. *See, e.g., Thomas Swan & Co. Ltd., v. Finisar Corp.*, C.A. 13-cv-178-JRG (E.D. Tex. Apr. 10, 2014) (attached as Ex. A to Gismervig Decl.); *Bonutti Skeletal Innovations LLC v. Arthrex, Inc.*, C.A. 6:13-cv-620-Orl-22TBS (M.D. Fla. March 25, 2014) (attached as Ex. B to Gismervig Decl.). Here, the Court

[3] To the extent that Plaintiffs are forced to further reduce the asserted claims, it is reasonable to also require a commensurate reduction in prior art references. *See, e.g., Masimo Corp.*, 918 F.Supp.2d 277, 286 (limiting plaintiffs to 30 asserted claims and limiting defendants to 40 prior art references).

is not undertaking a separate, pretrial claim construction process, and instead will render any claim construction ruling in the context of the evidence presented at trial. With that in mind, the appropriate time for Plaintiffs to make a final determination as to the further narrowed set of claims to take to trial is after expert discovery. At that point, the parties' respective claim construction positions and the corresponding extent to which the claims present distinct disputed issues will have crystallized. In other words, it is only after Plaintiffs see the actual evidence and arguments on which Defendants intend to rely at trial in support of their defenses that Plaintiffs will be in a position to assess which patent claims are the strongest, and which other claims can be discarded because they present duplicative issues. It would be unfair and highly prejudicial to force Plaintiffs to reduce the number of asserted claims yet again, before Defendants even disclose their expert evidence.

4. **If this Court Forces Endo to Limit its Asserted Claims at this Time, Endo Must be Allowed to Later Re-Assert Surrendered Claims**

The cases cited by Moving Defendants make one thing clear: if the Court mandates an early reduction in the number of asserted claims, Plaintiffs must be allowed to later modify that set of claims to adapt to changing circumstances. The Federal Circuit has found that a court imposed limitation on the number of asserted claims is only "permissible if the district court left open the door for the assertion of additional claims on a showing of need." *Stamps.com Inc. v. Endicia, Inc.*, 437 Fed. Appx. 897, 902 (Fed. Cir Aug. 1, 2011) (unpublished) (*citing In re Katz Interactive Call Processing Patent Litigation*, 639 F3d 1303, 1309-12 (Fed. Cir. 2011)); *see also Adobe Sys. Inc.*, 2013 WL 9541126, at *1 ("Adobe may re-assert any surrendered claims at a later date upon a showing of good cause."); *High Point SARL*, 2010 WL 9497168, at *5 ("[b]y directing plaintiff to identify a limited number of claims . . . the court does not absolutely preclude, at this point, plaintiff from asserting any of the 97-some remaining claims").

Accordingly, to the extent that this Court mandates an early reduction in the number of asserted claims, Plaintiffs must be allowed to modify their list of claims after reviewing Defendants' expert reports if good cause can be shown, for example, if Defendants present previously undisclosed theories or information.

But Endo does not believe that reducing claims now and allowing the list to change later is the most fair or efficient procedure. Modification of the list after expert reports would create otherwise unnecessary motion practice, and could force the parties to proceed to trial with claims that have not been adequately addressed by all sides' experts. These dilemmas are preventable if the Court adopts Endo's proposal for a staged reduction of claims.

CONCLUSION

For the reasons discussed above, the Court should not order Endo to further reduce its asserted claims at this time. Endo has already reduced its list by nearly 70%, and will further limit the asserted claims before trial, following the completion of expert discovery. Defendants' request that Endo be limited to a specific number of claims per patent now, instead of adopting Endo's proposed cap across the patents-in-suit after expert discovery, unreasonably restricts Endo's ability to select the most appropriate claims to be presented trial. Endo respectfully requests that instead the Court (1) adopt the proposed Case Management Order for the reasons set forth in its letters of August 14 and September 8, 2014; and (2) narrow the number of asserted claims and permitted prior art references in the manner set forth therein.

Dated: September 10, 2014

By: */s/ Jeff Fisher*

Jonathan D. Loeb
Carl Gismervig
Jeffrey Fisher
DECHERT LLP
2440 W. El Camino Real, Suite 700
Mountain View, CA 94040
(650) 813-4800
jonathan.loeb@dechert.com
carl.gismervig@dechert.com
jeffrey.fisher@dechert.com

Martin J. Black
Robert D. Rhoad
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104
(215) 994-4000
martin.black@dechert.com
robert.rhoad@dechert.com

ATTORNEYS FOR PLAINTIFF
ENDO PHARMACEUTICALS INC.